K014116

SonoSite
Imagine What You Can Do

DEC 2 0 2001

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510(K) Summary Of Safety And Effectiveness

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

Michael A. Hoffman
Director - Regulatory Affairs and Quality Systems
SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

(425) 951 – 1297

E-mail: michael.hoffman@sonosite.com

Date prepared: November 19 2001

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

SonoSite Hand-Carried Ultrasound System (subject to change)

Classification Names

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that System described in this Submission is substantially equivalent to a combination of the SonoSite Hand-Carried Ultrasound System (K010374), (K003399) and the Advanced Technology Laboratories (ATL) HDI® 5000 Ultrasound System (K961459). Where applicable, this new Submission references sections of K010374 and K003399 to signify that the sections remain the same as for those predicate devices.

4) Device Description:

The SonoSite Hand-Carried Ultrasound System is a highly portable, software-controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and display it on a monitor in 2D, M-Mode, Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, Color Power Doppler, PowerMap™ Directional Color Power Doppler, or in a combination of modes.

The System has an electrocardiography (ECG) display feature and supports a 3-lead ECG cable assembly to collect data. The SonoSite Hand-Carried Ultrasound System also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used for clinical diagnostic purposes.

The SonoSite Hand-Carried Ultrasound System is designed to accept curved or linear transducers of the types and frequency listed in the table below. All actions affecting the performance of the transducer are activated from the main system control panel.

Frequency Range:	2.0 - 10.0 MHz
Transducer Types:	Linear array Curved array Intracavitary array

The SonoSite Hand-Carried Ultrasound System is designed to comply with the standards listed below.

EN 60601-1:1997	IEC 61000-4-2:1999
EN 60601-1-1:1993	IEC 61000-4-3:1997
EN 60601-2-25:1996	IEC 61000-4-4:1995
EN 60601-1-2:1998	IEC 61000-4-5:1999
UL 2601-1:1999	ISO 10993
CAN/CSA C22.2, No. 601.1:1998	ISO 9001
CEI/IEC 61157:1992	EN 46001
RTCA/D0160D: 1997	21 CFR 820
CISPR11:1997	ANSI/AAMI EC53:1995 except for sections 4.4 and 4.5.9
JIS-T-100X-Series	Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1993
Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1998	European Active Medical Device Directive (93/42/EEC)
Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD2-1998	

5) Intended Use:

The intended uses of the SonoSite Hand-Carried Ultrasound System, as defined by FDA guidance documents, are:

Fetal - OB/GYN	Musculo-skeletal (conventional)
Laparoscopic	Musculo-skeletal (superficial)
Intraoperative (abdominal organs and vascular)	Neonatal Cephalic
Abdominal	Pediatric
Small Organ (breast, thyroid, testicle)	Cardiac (adult)
Trans-vaginal	Cardiac (pediatric)
Trans-rectal	Peripheral Vessel

Typical examinations performed using the SonoSite Hand-Carried Ultrasound System are:

Abdomen:

This system transmits ultrasound energy into the upper and lower quadrants of the abdomen of an adult or pediatric patient to obtain 2D, CPD, PowerMap DCPD, Tissue Harmonic Imaging, or PW and CW Doppler images, which can be used to assess the presence and extent of some diseases and injuries.

Small Parts And Superficial Structures:

This system transmits ultrasound energy into the superficial structures of body to obtain 2D, CPD, or PW Doppler images of normal structure and some pathologies of the breast, thyroid, superficial soft tissue, shoulder joints, wrist, ankle, and knee, which can be used to assess the presence and extent of some diseases and injuries.

Pediatric:

This system transmits ultrasound energy into the abdomen, pelvis and superficial structures of pediatric patients to obtain 2D, CPD, PowerMap DCPD, Tissue Harmonic Imaging, or PW and CW Doppler images of the abdominal organs, great vessels, pelvic structures, and pediatric hips, which can be used to assess the presence and extent of some diseases and injuries.

Cardiac:

This system allows the clinician to perform focused cardiac studies. This system transmits ultrasound energy into the thorax of adult and pediatric patients to obtain 2D, PowerMap DCPD, M-mode, Tissue Harmonic Imaging, or PW and CW Doppler images of the heart, great vessels, and anatomic or pathologic structures. This system can be used to assess overall cardiac performance and size, determine the presence and location of fluid around the heart and lungs, aid in pericardialcentesis and pleuralcentesis procedures, and visualize blood flow through cardiac valves. Also the system can be used to assess the presence and extent of some injuries and diseases. The ECG is used for accurate timing of diastolic and systolic function. The ECG trace is not used to diagnose cardiac rhythms and is not designed for long term cardiac rhythm monitoring.

Neonates:

Abdomen, cranium, pelvis and heart in neonates that weigh less than 1500 grams or are less than 32 weeks gestation: This system transmits ultrasound energy into the cranium, abdomen, pelvis soft tissue or heart of patients to obtain 2D, CPD, PowerMap DCPD, M-mode, or PW and CW Doppler images. These images will be used to assess the presence and extent of some diseases or

injuries. Some examples of the pathology that ultrasound is used for include: Cranium – hemorrhage, ischemia, shunt placement and dilated ventricles; Abdominal organs – renal disease, gallbladder disease; Pelvis – ovarian pathology, uterine pathology and testicular disease; Soft tissue/superficial tissue – hip, lymph nodes and superficial cysts.

GYN/Infertility:

This system transmits ultrasound energy into the lower abdomen or vagina of a female patient to obtain 2D, CPD, PowerMap DCPD, M-mode, Tissue Harmonic Imaging, or PW Doppler images of the reproductive system, which can be used to assess the presence and extent of disease in the female pelvic organs, monitor ovarian follicle size, and as an aid in chorionic villi sampling (CVS) procedures.

Obstetrics:

This system transmits ultrasound energy into the abdomen or vagina of a pregnant woman to obtain 2D, M-mode, Tissue Harmonic Imaging, or PW Doppler images of a fetus, which can be used to estimate gestational age, number and weight, and assess the presence and extent of disease and confirm viability. CPD or PowerMap DCPD imaging is intended for high-risk pregnant women. High risk pregnancy indications include, but are not limited to multiple pregnancy, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

WARNING:

CPD or PowerMap DCPD images can be used as an adjunctive method, not as a screening tool, for the detection of structural anomalies of the fetal heart and as an adjunctive method, not as a screening tool for the diagnosis of Intrauterine Growth Retardation (IUGR).

Prostate:

This system transmits ultrasound energy through the prostate of an adult patient to obtain 2D, CPD, or PW Doppler images of structures, which can be used to assess the presence and extent of disease or injury. Measurements are available to calculate the volume of the prostate gland.

Vascular:

This system transmits ultrasound energy into various parts of the body using 2D, CPD, PowerMap DCPD, Tissue Harmonic Imaging, or PW Doppler to obtain ultrasound images. The most common structures imaged are carotid arteries, deep veins in the arms and legs, great vessels in the abdomen, and peripheral line access, and interventional radiology purposes.

6) Technological Characteristics:

This device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-Mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, CW Doppler, Color Power Doppler, and PowerMap™ Directional Color Power Doppler) are the same as a combination of the predicate devices identified in item 3. Transducer patient contact materials are biocompatible.

This device conforms to the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA, 1998) for an on-screen display feature that provides information on potential thermal and cavitation bioeffect mechanisms. A user education program provides additional information so users may moderate the system's acoustic output in accordance with the ALARA (as low as reasonably achievable) principle.

The device's acoustic output limits are:

All applications:

I_{SPTA} (d)	720 mW/cm^2 (Maximum)
TIS/TIB/TIC	0.1 - 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)
I_{SPPA} (d)	0 - 700 W/cm^2 (Range)

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

SonoSite, Inc.
% Mr. Mark Job
510(k) Program Manager
TÜV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K014116
Trade Name: SonoSite Hand-Carried Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Product Code: 90 IYN
Regulatory Class: II
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: 90 IYO
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: 90 ITX
Dated: December 12, 2001
Received: December 14, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoSite Hand-Carried Ultrasound System, as described in your premarket notification:

Transducer Model Number

L25/10-5 10.0-5.0 MHz Linear Array
L52/10-5 10.0-5.0 MHz Linear Array
C11/7-4 7.0-4.0 MHz Curved Array
C15/4-2 4.0-2.0 MHz Curved Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

David A. Lepson

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

DEC 2 0 2001

K014116

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite Hand-Carried Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P	N		B+M; B+PWD; B+CWD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
	Pediatric	P	P	P	N		B+M; B+PWD; B+CWD	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal	P	P	P			B+M; B+PWD	Note 1
	Trans-vaginal	P	P	P			B+M; B+PWD	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	N		B+M; B+PWD; B+CWD	Note 1
	Cardiac Pediatric	P	P	P	N		B+M; B+PWD; B+CWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K010374.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014116

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite Hand-Carried Ultrasound System

Transducer: L25/10-5 10.0-5.0 MHz Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N			B+M; B+PWD	Note 1
	Abdominal	N	N	N			B+M; B+PWD	Note 1
	Intra-operative (Abdominal organs and vascular)	N	N	N			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic	N	N	N			B+M; B+PWD	Note 1
	Pediatric	N	N	N			B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles.)	N	N	N			B+M; B+PWD	Note 1
	Neonatal Cephalic	N	N	N			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N	N			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	N	N	N			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	N	N	N			B+M; B+PWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N			B+M; B+PWD	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K010374.

Prescription Use (Per 21 CFR 801.109)

David C. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014116

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite Hand-Carried Ultrasound System

Transducer: L52/10-5 10.0-5.0 MHz Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N			B+M; B+PWD	Note 1
	Abdominal	N	N	N			B+M; B+PWD	Note 1
	Intra-operative (Abdominal organs and vascular)	N	N	N			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic	N	N	N			B+M; B+PWD	Note 1
	Pediatric	N	N	N			B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles.)	N	N	N			B+M; B+PWD	Note 1
	Neonatal Cephalic	N	N	N			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N	N			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	N	N	N			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	N	N	N			B+M; B+PWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N			B+M; B+PWD	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K010374.

Prescription Use (Per 21 CFR 801.109)

David G. Segan

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014116

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite Hand-Carried Ultrasound System

Transducer: C11/7-4 7.0 – 4.0 MHz Curved Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	N		B+M; B+PWD; **B+CWD**	Note 1
	Intra-operative (Abdominal organs and vascular)						B+M	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	N		B+M; B+PWD; **B+CWD**	Note 1
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P	N		B+M; B+PWD; **B+CWD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
	Other (spec.)							

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Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K010374.

Prescription Use (Per 21 CFR 801.109)

David A. Legreen

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014116

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite Hand-Carried Ultrasound System

Transducer: C15/4-2 4.0 – 2.0 MHz Curved Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P	**N**		B+M; B+PWD; **B+CWD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P			B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	**N**		B+M; B+PWD; **B+CWD**	Note 1
	Cardiac Pediatric	P	P	P	**N**		B+M; B+PWD; **B+CWD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
	Other (spec.)							

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Prescription Use (Per 21 CFR 801.109)

David A. Seguine

(Division Sign-Off)
Division of **Reproductive, Abdominal,** and **Radiological Devices**
510(k) Number K014116